Attorney Docket No. 13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Appellants: Grooms, *et al.*

Serial No.: 09/905,683

Filed: July 16, 2001

For: "Multi-Component Cortical Bone Assembled Implant" (As Amended)

Group Art Unit: 3738

Confirmation No. 4376

Examiner: Bruce Edward Snow

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RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir,

In response to the Notification of Non-Compliant Appeal Brief that was mailed on November 11, 2007, Applicants hereby submit an amended Section V, providing a summary of the claimed subject matter mapping the independent claims on appeal explicitly to the specification by page, and line number and to the drawings if any. This submission is believed to be timely as it is being sent via Express mail within the one month period for response as set forth in the Notification of Non-Compliant Brief, ending on December 6, 2007.

Replacement Section V begins on page 2 of this submission.

Remarks begin on page 14 of this submission.

Replacement Section V

Section V below is intended to replace the original Section V of the appeal brief.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Pending independent claim 111 is directed to "[a]n assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion; a second cortical bone portion; said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient."[19]

Support for independent claim 111 can be found throughout the specification of the application as filed. For example, the Field of the Invention section of the application as filed states, "This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures, as well as methods for the manufacture and use thereof. Furthermore, this application relates to an assembled implant comprised of two or more individual segments fastened together."[20] As another example, the Detailed Description section of the application as filed provides the following description:

> For example, in a first such alternate method, implants of this invention are produced and then stacked to provide a unitary implant of the desired height dimensions. Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins.[21]

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[19] Claim 111, Claims Appendix.

[20] Exhibit 1, at p. 1, lines 18-21, Evidence Appendix. (Emphasis added).

[21] Exhibit 1, at p. 6, lines 6-11, Evidence Appendix. (Emphasis added).

Additional support can be found, for example, at p. 2, lines 22-24 ("cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure "); at p. 4, lines 15-19 ("shipment to physicians for use in implantation procedures"); at p. 4, lines 23-25 ("The implant is preferably formed from cortical bone"); at p. 6, lines 15-17 ("bringing halves of the implant into juxtaposition with each other"); at p. 19, lines 12-17 ("two implants 901 and 902 are retained in registered juxtaposition to form the implant 900"); at p. 19, lines 20-24 ("holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes"); at originally filed claims 11-16, 25-26, and 49-50; and at the Abstract at p. 37, lines 3-8 ("An implant composed substantially of cortical bone is provided").[22]

Further support for claim 111 can be found at Figures 7A and 7B, and the corresponding discussion thereof in the specification at pages 18-19:

> In FIG. 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow stacking thereof to achieve implants of various heights. Commencing from a blank cortical plug at the stage shown in FIG. 2D has the advantage that if breakage of the implant occurs during machining, this will likely occur prior to completion of all of machining steps. According to this embodiment of the invention, two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant). Each implant blank is placed in a drill jig, and by means of a drill press or like means, holes are drilled through the implants. With the implants still in the jig, the jig is placed on the table of an arbor press. Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins. In order to encourage bony ingrowth, channels may be cut into the adjacent surfaces of the implants. The embodiment shown in FIG. 7A is a top view of an implant 700 into which four holes 701-704 have been drilled. In FIG. 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B

[22] Exhibit 1, Evidence Appendix.

> have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed. Based on this disclosure, those skilled in the art will recognize that a number of variations and modifications may be made to stack various forms of bone implants, or to maintain such implants in register with each other. These modifications are to be considered within the scope of this invention.[23]

Pending claim 112 depends from claim 113, which depends from independent claim 111, and is directed to the "assembled bone implant of claim 113, wherein said first cortical bone portion and said second cortical bone portion each have a D shape."[24] Support for claim 112 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111, and as noted below for claim 113. Specific support for the elements of the first cortical bone portion and said second cortical bone portion each having a D shape can be found throughout the specification of the application as filed, including at p. 2, lines 17-25 ("substantially "D"-shaped cortical bone implant"); at p. 3, lines 3-7 ("the implant is derived from allograft or autograft cortical bone sources, is machined to form a substantially "D"-or other appropriately shaped implant"); at p. 4, lines 14-15 ("According to this invention, a substantially "D"-shaped cortical bone implant for cervical Smith-Robinson fusions is produced"); at p. 8, lines 13-26 ("It will be recognized that, based on the instant disclosure, a substantially "D"-shaped external profile of the implant may be machined by a variety of means"); at p. 10, lines 3-9 ("to provide a substantially "D"-shaped cortical bone implant with flat upper and lower surfaces"); at original claims 28 and 33; and at the Abstract at p. 37, lines 3-8 ("The implant is derived from allograft or autograft cortical bone sources, is machined to form a symmetrically or asymmetrically shaped (e.g. a substantially "D"-shaped) implant").[25]

Pending claim 113 depends from independent claim 111, and is directed to the "assembled bone implant of claim 111, wherein said first cortical bone portion is stacked

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[23] Exhibit 1, at p. 18, line 18 to p. 19, line 10, Evidence Appendix. (Emphasis added).

[24] Claim 112, Claims Appendix.

[25] Exhibit 1, Evidence Appendix.

over said second cortical bone portion."[26] Support for claim 113 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the first cortical bone portion being stacked over said second cortical bone portion can be found throughout the specification of the application as filed, including at p. 3, line 23 "FIG. 7 provides a view of a stacked embodiment of the implant"); at p. 3, line 27 to p. 4, line 3 "FIG. 9 provides a view of a stacked embodiment of the implant"); at p. 6, lines 6-11 ("implants of this invention are produced and then stacked to provide a unitary implant"); at p. 6, lines 11-15 ("Alternatively, the stacked implants may be retained in a unitary association by means of a plug of cancellous bone"); at p. 18, lines 18-20 ("to allow stacking thereof to achieve implants of various heights"); at p. 18, lines 22-25 ("two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced of a new desired height"); and at original claims 25 and 49.[27]

Pending claim 114 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium."[28] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-113. Specific support for the elements of the retention pin being selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium can be found throughout the specification of the application as filed, including at p. 6, lines 6-11 ("retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins"); and at p. 18, line 27 to p. 19, line 2 ("Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins").[29]

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[26] Claim 113, Claims Appendix.

[27] Exhibit 1, Evidence Appendix.

[28] Claim 113, Claims Appendix.

[29] Exhibit 1, Evidence Appendix.

Pending claim 115 depends from claim 114 and is a subset thereof. Claim 115 is directed to the "assembled implant of claim 114, wherein said retention pin is cortical bone."[30] Claim 115 is supported by the same disclosures in the specification that support claim 114, as described above.

Pending claim 116 depends from claim 111, and is directed to the "assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion."[31] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the first cortical bone portion being a mirror image of said second cortical bone portion can be found throughout the specification of the application as filed, including at p. 3, lines 24-26 ("juxtaposition of mirror image halves of the implant"); and at original claims 10, 16, 26 and 50.[32]

Pending claim 117 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein the implant has a beveled edge of defined radius."[33] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having a beveled edge of defined radius can be found throughout the specification of the application as filed, including at p. 10, lines 18-19 ("a beveled edge of defined radius is preferably machined into three faces of the implant"); at Figures 1C and 1D, and at the discussion of Figures 1C and 1D at p. 11, lines 5-10 ("In addition, a "radius" or bevel 115 is shown on the two side and posterior edges of the implant").[34]

Pending claim 118 depends from claim 115, and is directed to the "assembled implant of claim 115, wherein said first cortical bone portion and said second cortical

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[30] Claim 115, Claims Appendix.

[31] Claim 116, Claims Appendix.

[32] Exhibit 1, Evidence Appendix.

[33] Claim 117, Claims Appendix.

[34] Exhibit 1, Evidence Appendix.

bone portion are in a stacked position relative to one another."[35] Claim 118 is supported by the same disclosures in the specification that support claim 113, as described above.

Pending claim 120 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone."[36] Support for claim 120 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the first cortical bone portion and the second cortical bone portion being allograft bone can be found throughout the specification of the application as filed, including at p. 3, lines 3-7 ("the implant is derived from allograft or autograft cortical bone sources"); at p. 4, lines 23-25 ("The bone source... is preferably, allograft bone"); and at the Abstract, at p. 37, lines 3-8 ("The implant is derived from allograft or autograft cortical bone sources").

Pending claim 121 depends from claim 112, and is directed to the "assembled implant of claim 112, sized and shaped in the form of a cervical implant."[37] Support for claim 121 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant being sized and shaped in the form of a cervical implant can be found throughout the specification of the application as filed, including at p. 1, lines 18-21 ("This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures"); at p. 2, lines 17-25 ("The present invention provides a new cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure"); at p. 3, lines 3-7 ("An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures"); at p. 4, lines 14-15 ("a substantially "D"-shaped cortical bone implant for cervical Smith-Robinson fusions is produced"); and at the Abstract at p. 37, lines 3-8 ("An implant composed substantially of cortical bone is provided for use in

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[35] Claim 118, Claims Appendix.

[36] Claim 120, Evidence Appendix.

[37] Claim 121, Claims Appendix.

cervical Smith-Robinson vertebral fusion procedures. The implant is... inserted into the space between adjacent cervical vertebrae to provide support and induce fusion of the adjacent vertebrae").[38]

Pending claim 122 depends from claim 112, and is directed to the "assembled implant of claim 112, having a height between 7 and 14 mm."[39] Support for claim 122 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having a height between 7mm and 14 mm can be found throughout the specification of the application as filed, including at p. 5, lines 24-26 ("final implant heights from about 7 mm to about 14 mm may be produced"); at p. 18, lines 22-25 ("a unitary implant composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant)"); and at p. 24, lines 3-5 ("implants are provided having a height of between about 7 and 14 mm, a length of between about 11 and 14 mm and a width of between about 11 and 14 mm").[40]

Pending claim 123 depends on claim 111, and is directed to the "assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion."[41] Support for claim 123 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the or more retention pins comprising a cancellous bone portion can be found, for example, at p. 3, line 27 to p. 4, line 3:

> a stacked embodiment of the implant of this invention wherein the stacked constituents thereof are retained in registered relationship by press-fitting or otherwise bringing more than one implant into contact with each other and having a cancellous plug or other biocompatible material located in

[38] Exhibit 1, Evidence Appendix.

[39] Claim 122, Claims Appendix.

[40] Exhibit 1, Evidence Appendix.

[41] Claim 123, Claims Appendix.

> the central canal of each stacked implant, thereby acting as a retention pin.[42]

Additional support for the elements of the or more retention pins comprising a cancellous bone portion can be found throughout the specification of the application as filed, including at p. 6, lines 11-15 ("stacked implants may be retained in a unitary association by means of a plug of cancellous bone"); at Figure 9 and the discussion thereof at p. 19, lines 12-17 ("By press-fitting the two implants together using an appropriately shaped cancellous plug 905"); and at p. 22, lines 19-20 ("a cancellous plug").[43]

Pending claim 124 depends from claim 123, and is directed to the "assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP)."[44] Support for claim 124 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 123. Specific support for the elements of the cancellous bone portion being treated with a bone morphogenetic protein can be found throughout the specification of the application as filed, including at Figure 9 and the discussion thereof at p. 19, lines 12-17:

> By press-fitting the two implants together using an appropriately shaped cancellous plug 905 or a plug made from another biocompatible material, including but not limited to hydroxyapatite, cortical bone, synthetic materials, ceramic, optionally treated with growth factors such as bone morphogenetic protein and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.[45]

Pending claim 125 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said implant has two opposing surfaces that are inscribed

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[42] Exhibit 1, Evidence Appendix. (Emphasis added).

[43] Exhibit 1, Evidence Appendix.

[44] Claim 124, Claims Appendix.

[45] Exhibit 1, Evidence Appendix.

with teeth."[46] Support for claim 125 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having two opposing surfaces that are inscribed with teeth can be found throughout the specification of the application as filed, including at p. 3, lines 19-20 ("an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant"); at p. 10, lines 3-9 ("an external feature may be machined into the upper and lower surfaces.... This may be achieved by... ribbing or teeth into the upper, lower, or both surfaces of the implant"); at Figure 1D and the discussion thereof at p. 11, lines 5-10 ("the external feature 120 has the side profile of a set of teeth"); at Figure 5 and the discussion thereof at p. 16, lines 24-26 ("blades 502 for use in a broach assembly 500 for inscribing teeth into the top 110, bottom 111 or both surfaces of the implant"); at Figure 7 and the discussion thereof at p. 19, lines 4-6 ("In this view, the adjacent surfaces 710A and 710B have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed"); and at original claims 51 and 52.[47]

Pending independent claim 126 is directed to "A D-shaped assembled bone implant for implantation into a patient comprising: a first cortical bone portion having a D shape; and a second cortical bone portion having a D-shape; said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation."[48] Support for claim 126 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-113. For example, Figures 7A and 7B illustrate an implant including each of the elements recited in claim 126, and the discussion of these Figures

[46] Claim 125, Claims Appendix.

[47] Exhibit 1, Evidence Appendix.

[48] Claim 126, Claims Appendix.

on p. 18, line 18 through p. 19 line 17 of the specification of the application as filed describes how the first cortical bone portion and the second cortical bone portion are retained in stacked formation by through holes that receive retention pins.[49]

Pending claim 127 depends from claim 126, and is directed to the "assembled implant of claim 126, wherein said retention pin is a cortical bone pin."[50] Claim 127 is supported by the same disclosures in the specification that support claims 114-115, as described above.

Pending claim 128 depends from claim 126, and is directed to the "assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein."[51] Claim 128 is supported by the same disclosures in the specification that support claim 124, as described above.

Pending independent claim 129 is directed to "an assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion of allograft bone; a second cortical bone portion of allograft bone; said first cortical bone portion and said second cortical bone portion having one or more through holes sized and aligned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant outside the body of a patient as a unitary body suitable for implantation into a patient."[52] Claim 129 is supported throughout the specification of the application as filed. For example, the Field of the Invention section of the application as filed states, "This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures, as well as methods for the manufacture and use thereof. Furthermore, this application relates to an

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[49] See Exhibit 1, at Figures 7A and 7B, and at p. 18, line 18 to p. 19, line 7, Evidence Appendix.

[50] Claim 127, Claims Appendix.

[51] Claim 128, Claims Appendix.

[52] Claim 129, Claims Appendix.

assembled implant comprised of two or more individual segments fastened together."[53] As another example, the Detailed Description section of the application as filed provides the following description:

> For example, in a first such alternate method, implants of this invention are produced and then stacked to provide a unitary implant of the desired height dimensions. Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins.[54]

Additional support can be found, for example, at p. 2, lines 22-24 ("cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure "); at p. 4, lines 15-19 ("shipment to physicians for use in implantation procedures"); at p. 4, lines 23-25 ("The implant is preferably formed from cortical bone"); at p. 6, lines 15-17 ("bringing halves of the implant into juxtaposition with each other"); at p. 19, lines 12-17 ("two implants 901 and 902 are retained in registered juxtaposition to form the implant 900"); at p. 19, lines 20-24 ("holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes"); at originally filed claims 11-16, 25-26, and 49-50; and at the Abstract at p. 37, lines 3-8 ("An implant composed substantially of cortical bone is provided").[55] Further support for claim 129 can be found at Figures 7A and 7B, and the corresponding discussion thereof in the specification at pages 18-19.

Specific support for the elements of the first cortical bone portion and the second cortical bone portion being allograft bone can be found throughout the specification of the application as filed, including at p. 3, lines 3-7 ("the implant is derived from allograft or autograft cortical bone sources"); at p. 4, lines 23-25 ("The bone source... is

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[53] Exhibit 1, at p. 1, lines 18-21, Evidence Appendix. (Emphasis added).

[54] Exhibit 1, at p. 6, lines 6-11, Evidence Appendix. (Emphasis added).

[55] Exhibit 1, Evidence Appendix.

preferably, allograft bone"); and at the Abstract, at p. 37, lines 3-8 ("The implant is derived from allograft or autograft cortical bone sources").

Claims 130-136 ultimately depend from claim 129, and recite the same limitations as claims 112-118, respectively. Claims 130-136 are supported by the same disclosures in the specification that support claims 111-118, as described above.

In view of the foregoing discussion, the invention as claimed is fully supported by the application as originally filed.

Remarks

The Notification of Non-Compliant Appeal Brief indicated that the Brief on Appeal as originally submitted did not map the independent claim (129) on appeal explicitly to the specification by page and line numbers and to the drawings if any. An amended Section V has been provided, which maps the independent claim (129) to the specification and drawings.

Appellants believe that the deficiencies noted in the Notification of Non-Compliant Appeal Brief have been corrected, and respectfully submit that the amended Section V provided herewith places the Appeal Brief in Compliance.

Conclusion

Applicants believe that no fee is currently due with this Response to Notification of Non-Compliant Appeal Brief. The Commissioner is, however, hereby authorized to charge any necessary fees, or credit any overpayment, to Deposit Account 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

Dated: December 6, 2007

Respectfully submitted,

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